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# NASA Procedural Requirements

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(NASA Only)

## **Subject: Care and Use of Animals**

**Responsible Office: Office of the Chief Health & Medical Officer**

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## **Chapter 1. Responsibilities**

1.1 The NASA Chief Health and Medical Officer (CHMO) is the Authorized NASA Official (ANO) for the care and use of animals. The CHMO may delegate duties of the ANO to a senior individual in the office of the CHMO. The ANO shall be responsible for:

1.1.1 Implementing the provisions of this NPR and ensuring that all Agency programs and activities involving animals comply fully with all applicable laws, regulations, and guidelines;

1.1.2 Designating a NASA representative for the Interagency Research Animal Committee (IRAC);

1.1.3 Establishing and maintaining mechanisms for obtaining timely information from the Office of Laboratory Animal Welfare (OLAW) of all cases in which the assurance of an institution involved in NASA research has been withdrawn by the Public Health Service (PHS); and notifying NASA Institutional Animal Care and Use Committees (IACUC), Center Directors, Institutional Officials (IOs), and Research and Flight Program Managers of such revocations so that they can determine if NASA awards involving the use of animals are affected and take appropriate actions;

1.1.4 Reviewing all sanctions imposed by Center Directors or IACUCs' to determine if further sanctions are warranted, or, at his or her discretion, initiating investigations of alleged noncompliance with this NPR and imposing sanctions when warranted;

1.1.5 Appointing the NASA Chief Veterinarian, who shall be a NASA civil servant or appointed under the Intergovernmental Personnel Act (IPA) provision and shall report to the ANO;

1.1.6 Establishing and maintaining mechanisms to notify the NASA Chief Veterinarian,

NASA IACUCs, Center Directors, IOs, and Research and Flight Program Managers of reports of noncompliance with the Animal Welfare Act (AWA), PHS, and this NPR that are received from nonNASA institutions where animal research is supported by NASA; and

1.1.7 Designating a NASA representative(s) for the Committee on Space Research (COSPAR) Panel on the Care and Use of Animals in Space-borne Research.

1.2 The NASA Animal Policy Review Board (APRB) shall be responsible for meeting in person at least once per year and convening via a teleconference at least once each calendar year to accomplish the following:

1.2.1 Reviewing and reaffirming that animal research, testing, and training are activities necessary for the achievement of NASA goals and objectives;

1.2.2 Reviewing and reaffirming the "NASA Principles for the Ethical Care and Use of Animals";

1.2.3 Reviewing animal care and use policies and procedures, issues, and this NPR;

1.2.4 Cooperatively developing common procedures, guidance, training, documentation, and forms which provide uniform and progressive application of professionally accepted standards at all NASA Centers involved in animal care and use activities;

1.2.5 Reviewing each Center's Animal Care and Use Program at least once annually, through a review of the Center's semiannual IACUC reports and other information as needed;

1.2.6 Coordinating the Center's Animal Care and Use Handbooks, IACUC Reference Manuals, animal care and use protocol form, and Animal Care and Use Standard Operating Procedures Workbooks to maximize commonality;

1.2.7 Exchanging information regarding issues and practices pertaining to animal care and use;

1.2.8 Recommending changes in NASA policies and procedures to the ANO and Center Directors, as appropriate;

1.2.9 Serving as a source of expertise and advocacy on animal care and use issues for the ANO, IACUC's, and NASA management; and

1.2.10 Assisting the ANO in developing responses to public, organizational, and legislative inquiries and comments about NASA animal activities.

1.3 The NASA Flight Animal Care and Use Panel (NFACUP) shall be responsible for the following:

1.3.1 Reviewing and providing policy concurrence on all protocols using animals that are associated with space flight activities supported by NASA. No NASA-supported space flight activity using animals will be conducted without such review and concurrence by the NFACUP. The NFACUP may disapprove animal activities, but may not approve an activity related to the care and use of animals if the activities have not been approved by the appropriate Center IACUC;

1.3.2 Providing Agency animal care and use policy approval for space flight activities;

1.3.3 Providing assurance to the ANO that all animal research conducted in space flight

meets the requirements of all applicable Federal regulations, and that a comprehensive review of benefits and risks has been completed; and

1.3.4 Assuring NASA compliance with the COSPAR "Policy and Guidelines for the Use and Care of Animals in Space-borne Research."

1.4 Center Directors shall be responsible for the following:

1.4.1 Signing the Center's Animal Welfare Assurance, making a commitment on behalf of the Center that the requirements of this NPR will be met. Center Directors may delegate authority for the day-to-day management of their Center's Animal Care and Use Program, but they retain the ultimate responsibility for ensuring compliance with the AWA, PHS Policy, the Guide, and this NPR at their Centers. In addition, only Center Directors may appoint personnel to the IACUC.

1.4.2 Serving as the Center's IO or delegating, in writing, an IO who meets the requirements of the PHS Policy and AWA to perform the following:

1.4.2.1 Establishing and supervising the functioning of their Centers' IACUC. This responsibility may be accomplished through the use of another Center's IACUC via a formal intercenter agreement;

1.4.2.2 Signing and submitting to OLAW the AWA, committing the Center to the requirements of the PHS Policy and this NPR in all Center activities involving animals. Providing copies of the approved AWA, OLAW letter of approval, and any OLAW correspondence to the ANO;

1.4.2.3 Approving and signing the application for Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International Accreditation and the annual AAALAC International reports. Providing copies of the AAALAC International Accreditation letter, the annual reports, and any correspondence from AAALAC International to the ANO;

1.4.2.4 When applicable, approving the annual report to the U.S. Department of Agriculture (USDA) and providing copies of the report and any comments from USDA to the ANO;

1.4.2.5 Deciding and administering sanctions in cases of noncompliance with this NPR, in accordance with the AWA, its implementing regulations, PHS Policy, and NASA personnel policies; and notifying appropriate funding officials and the ANO; and

1.4.2.6 Providing the ANO with copies of all IACUC minutes and reports.

1.5 The NASA Chief Veterinarian shall be responsible for the following:

1.5.1 Coordinating veterinary and animal care activities across NASA institutions. In accomplishing this responsibility, the NASA Chief Veterinarian is specifically authorized to halt any animal activity he or she believes to be noncompliant with applicable laws, regulations, this NPR, and approved protocols. Following halting of any activity, the NASA Chief Veterinarian will initiate action, including IACUC re-review, to resolve the situation;

1.5.2 Guiding, as Chairperson, the activities of the APRB;

1.5.3 Advising the ANO on any aspect of the Agency's Animal Care and Use Program;

1.5.4 Representing NASA in the external Laboratory Animal Science community and associations;

1.5.5 Participating in the development, review, and approval of requirements for all animal facilities and equipment for flight as related to animal care and use;

1.5.6 Maintaining coordination with the International Council for Laboratory Animal Science (ICLAS) and COSPAR;

1.5.7 Informing international entities and individuals about the technical requirements in accordance with U.S. laws, regulations, guidelines, standards, and this NPR. This will include information regarding the requirements and constraints for flight animal research activities; and

1.5.8 Serving as the Chair of the NFACUP.

1.6 IACUC shall be responsible for the following:

1.6.1 Performing responsibilities in accordance with provisions given in the Animal Welfare Act, its implementing regulations, PHS policy, and the Guide;

1.6.1.1 The IACUC at the Ames Research Center (ARC) is charged with reviewing all space flight activities and any supporting ground-based activities;

1.6.1.2 When animals are housed at a NASA Center (host Center), the host Center's IACUC is responsible for their care and use and for reviewing, approving, or disapproving those parts of proposals that call for the use of the Center's facilities housing the animals; and

1.6.1.3 Although in-flight spacecraft may contain facilities that are by definition "Animal Facilities," it is recognized that IACUC inspection of such facilities are impractical and often impossible. However, to meet the intent of the AWA in regards to monitoring animal facilities, the ARC IACUC, and IACUC of the Center that developed and/or managed the in-flight hardware or facilities, will review all in-flight and post-flight crewmember's reports regarding animal hardware performance. Any reported deficiency or failure must be evaluated by the ARC IACUC and host Center's IACUC in regards to the welfare of animals being maintained in flight. Any deficiency or failure determined to potentially impact animal well-being negatively will be reported immediately to the appropriate Center Director, the NASA Chief Veterinarian, and the ANO. OLAW will also be notified of such deficiencies or failures if the in-flight animal activities involve PHS funding.

1.6.2 Approving, disapproving, or requiring modifications to be made in those components of proposed activities involving the care and use of animals that are submitted by investigators. In addition, IACUC's have the authority to suspend previously approved activities involving animals. All decisions shall be based on the response of a majority of a quorum of the members present and shall be accurately recorded in the minutes of the meeting. In conducting the reviews of proposed activities involving animal care and use, IACUC members will ensure that the "NASA Principles for the Ethical Care and Use of Animals" are met.

1.6.2.1 Animal activities that have been approved by the IACUC may be subject to further review by the Center Director, ANO, or other NASA officials, as appropriate. These officials may disapprove animal activities but may not approve an activity related to the care and use of animals if the activities have not been approved by the IACUC.

1.6.3 Including in its membership, in accordance with the AWA and its implementing regulations, and PHS Policy, at least one Doctor of Veterinary Medicine with training or experience in Laboratory Animal Medicine and who has direct or delegated program authority for activities involving animals, a practicing scientist experienced in research involving animals, an individual not affiliated with the institution in any way other than as a member of the IACUC, and at least one member whose primary concern is in a nonscientific area such as an ethicist, lawyer, or member of the clergy.

1.6.4 Approving personnel qualifications and training.

1.6.5 Reviewing the Center's program for humane care and use of animals, at least once every 6 months, and inspecting all of the Center's animal facilities (including satellite facilities), using the AWA and its implementing regulations, PHS Policy, and the Guide as a basis for evaluation. The report, signed by a majority of the IACUC members, must be submitted to the ANO through the IO.

1.6.5.1 Reports of the reviews and inspections must contain a description of the nature and extent of the Center's adherence to the AWA, its implementing regulations, PHS Policy, the Guide, and this NPR. They must specifically identify any departures from the provisions of the Guide and this NPR and must state the reasons for each departure. In addition, they must contain specific reference to the Committee's efforts to incorporate bioethical considerations in their reviews of proposed animal care and use activities.

1.6.5.2 The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, consistent with PHS Policy definitions, and, in the judgment of the IACUC and the Center Director, is or may be a threat to the health or safety of the animals. The IACUC, through the IO, will report promptly any such deficiencies to OLAW.

1.6.5.3 If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.

1.6.6 Reviewing and approving, requiring modifications in (to secure approval), or withholding approval of those components of proposed activities or significant changes to ongoing activities related to the care and use of animals. Once approved, no significant changes can be made until a written request with appropriate justification is submitted to and approved by the IACUC.

1.6.7 Conduct continuing reviews of approved animal activities at appropriate intervals as determined by the IACUC, but at least once every 12 months.

1.6.8 Establishing mechanisms for ensuring the reporting, receipt, and review of concerns involving the care and use of animals.

1.6.9 Making recommendations to the IO regarding any aspect of the Center's animal program, facilities, or personnel training.

1.6.10 Providing copies of meeting minutes and reports of semiannual inspections and reviews to the IO who will forward copies, with any recommendations pertaining to Agency-wide issues, to the ANO and the NASA Chief Veterinarian.

1.6.11 Reporting, in writing, the following to the ANO, as well as USDA, the Animal and Plant Health Inspection Service (APHIS), and OLAW as required, through the IO, at least once every 12 months:



- 1.6.11.1 Changes in the description of the Center's program for animal care and use;
- 1.6.11.2 Changes in the Center's program or facilities that would affect the AAALAC International accreditation status;
- 1.6.11.3 Changes in the IACUC membership;
- 1.6.11.4 A statement that the Center has no changes to report, if there are no changes; and
- 1.6.11.5 Any recommendations, including minority views, for changes in NASA-wide facilities, policies, or procedures.
- 1.6.12 Promptly provide, through the IO, the ANO, as well as USDA, APHIS, and OLAW, as appropriate, with a full explanation of the circumstances and actions taken, with minority views, if any, with respect to the following:
  - 1.6.12.1 Any deviation resulting in serious or continuing noncompliance with the provisions of the Guide, AWA, its implementing regulations, PHS Policy, or this NPR;
  - 1.6.12.2 The reasons for any suspension or termination of approval will be documented in writing with copies provided promptly to the Principal Investigator (PI), the Center Director, OLAW, and the ANO. If an IACUC suspends a research activity that has already been approved, the PI will be given written documentation regarding the reason for such action and will be afforded the opportunity to take corrective actions to resolve the situation; and
  - 1.6.12.3 Any adverse actions by, or communication from OLAW, AAALAC International, or USDA.
- 1.7 The Institutional Review Board (IRB), Committee for the Protection of Human Subjects, at Johnson Space Center (JSC), if the experiment involves the exposure of the crewmembers to research animals, shall review and approve the proposal and modifications to ensure the protection of the crew from exposure to zoonotic risk and other health-related concerns. The IRB may also review proposals and modifications to ensure that the orbiter and flight hardware will not be chronically contaminated by zoonotic agents potentially carried by research animals. Copies of documents indicating IRB action in regards to projects involving animals will be provided to the ANO and the responsible IACUC(s).
- 1.8 Animal Care and Use of Animals personnel shall be responsible for the following:
  - 1.8.1 Maintaining animals in accordance with contemporary standards, laws, and regulations;
  - 1.8.2 Obtaining and maintaining, through training and experience, proficiency in regards to the procedures they perform involving animals; and
  - 1.8.3 Reporting any deficiencies in procedures for animal care and use activities or issue of noncompliance with applicable laws, this NPR, and IACUC approvals to the veterinarian, IACUC chairperson, NASA line management, or NASA Inspector General.
- 1.9 PIs, including those resident at NASA Centers, shall be responsible for the following:
  - 1.9.1 Complying with, and ensuring their research staff comply with, those responsibilities applicable to all animal care personnel described above in section 1.8;

1.9.2 Obtaining IACUC approval from each institution where research will be conducted for all successfully peer-reviewed proposals requesting the use of animals. NASA will not provide support for proposals that have passed peer review until proof of IACUC approval is submitted. In the case of international investigators, proof of approval for the use of animals must be provided by a governmental or agency level equivalent of an IACUC;

1.9.3 Including the PHS AWA number from OLAW for the institution at which the research is to be conducted. Proposals from U.S. and foreign institutions without an approved assurance on file with the National Institutes of Health (NIH) OLAW must provide one of the following: 1) proof of current accreditation from AAALAC International; 2) documentation of institutional animal care and use ensuring compliance with the PHS Policy; or 3) documentation of institutional animal care and use ensuring compliance with the Council for International Organization of Medical Sciences (CIOMS), "International Guiding Principles for Biomedical Research Involving Animals;" and

1.9.4 Conducting all animal activities in accordance with approved Animal Care and Use Protocols.

1.9.4.1 NASA employees who wish to conduct research using animals at a nonNASA facility must provide documentation to the IACUC at their Center stating that the research has been approved by the IACUC at the institution where the work will be conducted.

1.9.5 Providing results to the IACUC, particularly those results, outcomes, and assessments of animal condition and health, that will allow the IACUC to continually monitor the adequacy of animal well-being and unintended consequences which adversely affected animal well-being.

1.9.6 Using experimental designs and procedures that accomplish the following:

1.9.6.1 Minimize the numbers of animals necessary to obtain scientifically valid results;

1.9.6.2 Incorporate refined techniques that eliminate or minimize animal pain and distress;

1.9.6.3 Replace animals with no animal systems whenever possible; and

1.9.6.4 Notifying Program/Project Managers and the responsible IACUC, in writing, of deviations, unexpected outcomes, or proposed significant changes in approved protocols.

1.10 PIs and NASA personnel working in nonU.S. laboratories under NASA sponsorship are responsible for the following:

1.10.1 Conducting all animal activities in accordance with the animal care and use standards as defined in this NPR, the PHS Policy, the AWA, its implementing regulations, or as defined by the host country, whichever is more demanding;

1.10.2 Not participating in animal activities if the standards defined in this NPR, the PHS Policy, the AWA and its implementing regulations, or the standards of the host country cannot be met; and

1.10.3 Reporting as soon as possible, with followup hard copy, their decision that they cannot participate in animal activities to the NASA Program Manager, appropriate Center Director, the appropriate IACUC, the NASA Chief Veterinarian, and the ANO.

1.11 Program and Project Managers shall be responsible for the following:

1.11.1 Determining that Investigators and PIs comply with subsections 1.9 and 1.10 of this NPR and withholding funding from those that do not;

1.11.2 Ensuring that NASA has received documentation that proposals requesting NASA support for activities comply with subsection 1.9 of this NPR and certifying compliance to the selection official prior to providing NASA support; and

1.11.3 Ensuring that space flight activities comply with Chapter 4 of this NPR and certifying compliance to the selection official prior to selection for NASA support.

1.12 Attending veterinarians at NASA Centers shall be responsible for the following:

1.12.1 Managing and providing the clinical veterinary care program to include all requirements specified as "Adequate Veterinary Care" in the AWA's implementing regulations and PHS Policy;

1.12.2 Serving as a voting member of the Center's IACUC;

1.12.3 Ensuring that all animal care and use activities are monitored and the attending veterinarian is aware of the results of such monitoring;

1.12.4 Maintaining surveillance of the health and condition of animals in the animal colony and those being used in research activities;

1.12.5 Reporting any unresolved deficiencies in animal care, use, and treatment, or any activity that is not being conducted in accordance with the description of that activity provided by the PI and approved by the IACUC, to the Center Director, IACUC, and the NASA Chief Veterinarian;

1.12.6 Immediately halting activities deviating from IACUC-approved practices or procedures, or from professionally accepted animal care and use practices. In cases where the differences between the investigator or animal care provider and the veterinarian cannot be resolved within 24 hours, the matter must be immediately brought to the attention of the IO and IACUC Chair for review and resolution;

1.12.7 Participating in the training of personnel in the handling of animals and in specimen sampling procedures and other professionally accepted standards of animal care and use;

1.12.8 Overseeing all schedules and procedures for training and acclimating animals;

1.12.9 Reviewing presurgical, surgical, and postsurgical procedures to verify that the principles of the Guide for survival surgery are used. When necessary, the veterinarian will provide or arrange for training necessary to qualify investigators and other animal users;

1.12.10 Reviewing and verifying the appropriateness of all veterinary medical and experimental procedures performed on animals; and

1.12.11 Reviewing and approving, in consultation with the NASA Chief Veterinarian, the design requirements and changes of local animal facilities for support of ground and space flight animal activities.

1.13 Selection officials, as the individuals selecting or approving grants, contracts,



agreements, awards, and reimbursable arrangements shall be responsible for the following:

1.13.1 Ensuring that investigators have IACUC approval from their home institution and that, if applicable, their home institution has an approved OLAW assurance or meets the criteria of section 1.9.3 prior to funding of any animal-related activities, and

1.13.2 Including a copy of this NPR with each request for proposal and notification of selection.

1.14 Crewmembers serving as the animal care personnel during a flight activity shall be responsible for the following:

1.14.1 Participating in assigned preflight training to gain proficiency in accomplishing activities and procedures involving animals;

1.14.2 Providing scheduled status reports to the duty veterinarian or NASA Chief Veterinarian on animal health and well-being during in-flight operations;

1.14.3 Reporting promptly to the duty veterinarian or NASA Chief Veterinarian any problems affecting animal welfare during space flight, such as deficiencies in hardware or in procedures for animal care and use;

1.14.4 Providing the NASA Chief Veterinarian with in-flight and postflight reports regarding hardware performance and animal care and use procedures; and

1.14.5 Ensuring that animal welfare requirements receive priority during the conduct of flight activities.

1.15 The duty veterinarian or NASA Chief Veterinarian shall have the responsibility and authority to serve as the attending veterinarian during space flight activities.

1.15.1 The Chief Veterinarian or designated duty veterinarian has sole authority in all matters related to the euthanasia of animals during a mission.

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